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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,679	09/26/2003	Juan F. Granada	94510-010200/US	9812

35893 7590 02/12/2007
GREENBERG TRAURIG, LLP
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ATTN: PATENT ADMINISTRATOR
BOSTON, MA 02110

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/672,679

Applicant(s)

GRANADA ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 78-95 and 105-175 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 78-95, 97-111, 113-134, 136-156 and 160-175 is/are rejected.
- 7) ☒ Claim(s) 14, 112, 135 and 157-159 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/03; 7/26/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 16-77, 96-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/25/05. Claims 16-77 and 96-104 have been canceled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 15, 78-79, 93-95, 105-111, 113-120, 125-134, 136-144, 150-156, 160-167, 172-173 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitbourne et al. 2002/0018795. Whitbourne et al. discloses the invention as claimed comprising:

A biocompatible drug release matrix for a medical device comprising: a biocompatible polymer matrix; and a drug incorporated into the biocompatible polymer matrix, wherein the biocompatible polymer matrix is co-solubilized with the drug in a solvent to form a solution and the solvent is evaporated from the solution see [0065 example 3];

wherein the drug has antibiotic properties and anti-proliferative properties see section [0059];

wherein the drug is an analogue related to the quinone-containing alkylating agents of a mitomycin family; the biocompatible drug release matrix of claim 1 wherein the drug is mitomycin C (see [0059];

wherein a ratio of the weight of the biocompatible polymer matrix and the drug is *about* 4 to about 1, see section [0026]);

wherein the solvent is selected from the group consisting of water, saline, tetrahydrofuran, methanol, acetone, butyl acetate, cyclohexane, carbon tetrachloride, ether, chloroform, benzene, ethanol, toluene, dimethyl sulfoxide, petroleum ethers, other hydrocarbons and other organic solvents see section [0052];

wherein the biocompatible polymer matrix comprises polyvinyl pyrrolidone with an at least one isocyanate;

wherein the biocompatible polymer matrix comprises a mixture of hydrophilic and hydrophobic polymers selected from the group consisting of polyurethanes, polyvinyl pyrrolidone, poly methyl methacrylate (PMMA), hydroxyethyl methacrylate and cellulose esters;

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wherein the biocompatible polymer matrix comprises an erodible polymer ;

wherein the erodible polymer is selected from the group consisting of polyactide, polyactide with glycolide, polyesteramides, polyurethanes, poly(ethylene-urethane), poly(ester-urethane) and poly(ether-polyester-urethane), amino-acid based polyurethanes, polycaprolactone based polyurethanes, polyurethanes synthesized from poly(butylene succinate) polyol, poly(ethylene glycol), and 4,4'-methylenebis(cyclohexyl isocyanate), fat, carbohydrates and protein compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 80-92, 119, 121-124, 145-148, 168-170, 174-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. in view of Rypacek et al. 7,160,592. Whitbourne et al. has been disclosed above and while Whitbourn et al. does teach that the polymer matrix incorporated with a drug may be applied to a substrate or scaffold they do not specifically state that it is for a vascular prosthesis or the specify rates of release of the drugs. Rypacek et al. 7,160,592 teach a polymer matrix which is

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also co-solubilized with a drug and evaporated in a solvent solution. See col. 3, lines 62-67 4, lines 1-42; and col. 27, lines 25-33 col. 30, lines 26-47 and "burst time" col. 29, lines 61-67. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the medical device application of Whitbourne et al. and incorporate the time released properties as claimed and shown by Rypacek in order to custom tailor the prosthesis to immediate and lasting therapies to the site of implantation.

Allowable Subject Matter

Claims 14, 112, 135, 157-159 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

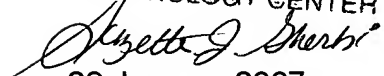
The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUZETTE GHERBI
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700


29 January 2007